K111657

JUN 23 2011

5 Summary of Safety and Effectiveness

I. General Information:

Submitter's Name and Address:	Medtronic, Inc. Medtronic Perfusion Systems 8200 Coral Sea Street NE Mounds View, MN 55112
Contact Person:	Lisa Stone Principal Regulatory Affairs Specialist Tel: 763-514-9866 Fax: 763-367-8360 Email: lisa.j.stone@medtronic.com
Date of Summary:	June 13, 2011
Proprietary Name of Device:	Affinity™ CP Centrifugal Blood Pump with Balance™ Biosurface (model BBAP40)
Common/Usual Name:	Centrifugal Blood Pump
Classification Name:	Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Classification:	Class III, 21 CFR 870.4360
Product Code:	KFM
Predicate Device:	Affinity™ CP Centrifugal Blood Pump Model AP40 (K100631) Affinity Pixie™ Arterial Filter with Balance™ Biosurface Model BB4014 (K100646)

II. Device Description:

The Affinity™ CP Centrifugal Blood Pump with Balance™ Biosurface is intended to be used in medical procedures requiring extracorporeal circulation circuits. Functionality and intended use of the coated pump are the same as those for the

uncoated pump. The pump is designed to move blood by centrifugal force generated by a combination of a smooth rotating cone and low-profile impeller fins. Energy is transferred from the pump in the form of pressure and velocity as the blood is driven toward the outlet port of the pump. The pump utilizes a pivot bearing design on a dual ceramic pivot.

The Affinity CP Centrifugal Blood Pump with Balance Biosurface is coated with a nonleaching biocompatible surface to reduce platelet activation and adhesion and preserve platelet function.

As with the uncoated Affinity CP pump the Affinity CP Centrifugal Blood Pump with Balance Biosurface is driven by the External Drive Motor or the Emergency Handcrank (K100631). There have been no changes to these accessory devices.

III. Intended Use:

The AFFINITY CP Centrifugal Blood Pump with Balance Biosurface is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours).

It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (e.g., valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants).

The AFFINITY CP Centrifugal Blood Pump with Balance Biosurface is driven by the External Drive Motor or the Emergency Handcrank.

IV. Comparison to Predicate Devices:

The Affinity CP Centrifugal Blood Pump with Balance Biosurface is substantially equivalent to the predicate uncoated Affinity CP Centrifugal Blood Pump, in that its intended use and design are exactly the same. The only difference is the addition of Balance Biosurface to the blood contacting surfaces of the pump. The Balance Biosurface is exactly the same as that used on the Affinity Pixie Arterial Filter with Balance Biosurface.

V. Summary of Performance Data:

Verification and validation testing has demonstrated that the Affinity CP Centrifugal Blood Pump with Balance Biosurface is substantially equivalent to the predicates. Performance testing included: flow rates, heat generation,

maximum differential pressure, maximum rotational speed, noise generation, duration of performance, hydraulic performance, pivot bearing wear, prime volume, sterilization, biocompatibility, hemolysis, bioactivity, coating leaching and coverage.

VI. Conclusion:

Based on the accumulated technical information, intended use, verification tests and performance data provided, the Affinity CP Centrifugal Blood Pump with Balance Biosurface is substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 23 2011

Medtronic, Inc.
c/o Ms. Lisa Stone
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K111657
Trade/Device Name: Affinity™ CP Centrifugal Blood Pump with Balance™ Biosurface (Model BBAP40)
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller type cardiopulmonary bypass blood pump
Regulatory Class: Class III
Product Code: KFM
Dated: June 13, 2011
Received: June 14, 2011

Dear Ms. Stone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Statement of Indications for Use

510(k) Number: K111657

Affinity™ CP Centrifugal Blood Pump with Balance™ Biosurface (model BBAP40)

Indications for use:

The Affinity™ CP Centrifugal Blood Pump with Balance™ Biosurface is used to pump blood through the extracorporeal bypass circuit for extracorporeal circulatory support for periods appropriate to cardiopulmonary bypass (up to 6 hours).

It is also indicated for use in extracorporeal support systems (for periods up to 6 hours) not requiring complete cardiopulmonary bypass (e.g. valvuloplasty, circulatory support during mitral valve reoperation, surgery of the vena cava or aorta, liver transplants).

The Affinity™ CP Centrifugal Blood Pump with Balance™ Biosurface is driven by the External Drive Motor or the Emergency Handcrank.

Prescription Use ___x___ **OR** **Over-The-Counter-Use** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111657